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ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR TETSUYA YANO 35.C13982 6685 09/430,029 10/29/1999 **EXAMINER** 5514 05/19/2004 SLOBODYANSKY, ELIZABETH FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA ART UNIT PAPER NUMBER NEW YORK, NY 10112 1652 DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	09/430,029	YANO ET AL.
	Examiner	Art Unit
	Elizabeth Slobodyansky, PhD	1652
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
1) Responsive to communication(s) filed on <u>9 February 2004</u> .		
2a)⊠ This action is <b>FINAL</b> . 2b)□ This action is non-final.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is		
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4)⊠ Claim(s) <u>1-48 and 55-57</u> is/are pending in the application.		
4a) Of the above claim(s) is/are withdrawn from consideration.		
5)⊠ Claim(s) <u>1,2,6-8,15,16,19,20 and 56</u> is/are allowed.		
6)⊠ Claim(s) <u>3-5, 9-14, 17, 18, 21-48, 55 and 57</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement.		
Application Papers		
9) The specification is objected to by the Examiner.		
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).		
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a) ☐ All b) ☐ Some * c) ☐ None of:		
<ol> <li>Certified copies of the priority documents have been received.</li> </ol>		
2. Certified copies of the priority documents have been received in Application No		
3. Copies of the certified copies of the priority documents have been received in this National Stage		
application from the International Bureau		
* See the attached detailed Office action for a list of the certified copies not received.		
Attachment(s)		
1) Notice of References Cited (PTO-892)	4) 🔲 Interview Summary Paper No(s)/Mail Da	
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) 🔲 Notice of Informal P	atent Application (PTO-152)
Paper No(s)/Mail Date	6)	

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#### **DETAILED ACTION**

The amendment filed February 9, 2004 amending claims 1, 3, 6-11, 13, 15, 17, 19 and 55 and adding claims 56 and 57 has been entered.

Claims 1-48 and 55-57 are pending.

### Claim Objections

Claims 21, 22, 28 and 57 are objected to because of the following:

Claim 57 recites "any one of Claims 6, 7, 9 and 56" whereas claim 55, for example, recites "any one of Claims 6, 7, 9 or 56" (emphasis added). Similarly, claims 21, 22 and 28, for example, recite "any one of claims 15, 17 and 19". It is suggested that applicants maintain consistency throughout the claims and refer to "any one of Claims 6, 7, 9 or 56", for example.

Claim 57 recites "toluene monooxygenase encoding region of 4.9 kb or less is functionally converted to the promoter" where it appears "toluene monooxygenase encoding region of 4.9 kb or less is functionally connected top the promoter" is intended.

Appropriate correction is required.

#### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 3-5, 9-14, 17, 18, 21-48, 55 and 57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 3-5, 9-14, 17, 18, 21-48, 55 and 57 have been amended to recite "wherein the first and second DNA fragments include deletion, substitution or addition of one to four bases". While there is support in the specification for "one" base, the examiner is unable to locate adequate support in the specification for "four bases".

Applicants indicate support for the amendment in Examples 6 and 7 where four primers introduced the Ncol site (Remarks, page 16). While said description may provide support for the specific sequences, the description of the specific sequences does not provide support for the entire claimed genus. Thus there is no indication that DNA fragments that "include deletion, substitution or addition of one to four bases" were within the scope of the invention as conceived by Applicants at the time the application was filed.

Accordingly, Applicants are required to cancel the new matter in the response to this Office Action.

## Allowable Subject Matter

Claims 1, 2, 6-8, 15, 16, 19, 20 and 56 are allowed.

## Response to Arguments

Applicant's arguments filed February 9, 2004 have been fully considered.

The outstanding rejections are withdrawn in view of the amendment limiting the structure of the sequences.

#### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The

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fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth Slobodyansky, PhD

Primary Examiner Art Unit 1652

May 13, 2004